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APR 27 2007

510(K) Summary

Introduction

This 510(k) summary documentation is intended to comply with requirements of 21 CFR § 807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510K Submitted By

Generic Medical Device, Inc.
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USA Contact Person

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Consultant
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Date Prepared

December 28, 2006

Trade Name of Device

Universal Surgical Mesh

Proprietary Name:

Universal Surgical Mesh

Common Name:

Surgical Mesh

Classification Name:
Surgical Mesh
Class II: General & Plastic Surgery
21 CFR 878.3300, Product Code FTL.

Predicate Devices:
K962530- PROLENE Polypropylene Mesh Nonabsorbable Synthetic
Manufactured by:
Ethicon, Inc.
Somerville, New Jersey 08876-0151

510(k) Classification
Class II

Device Description

Universal Surgical Mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE Polypropylene Mesh Nonabsorbable Synthetic Surgical Mesh (ETHICON, INC). The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue in-growth.

Universal Surgical Mesh in knitted by a process that interlinks each fiber junction and provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Intended Use
The Universal Surgical Mesh is intended for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Comparison to Predicate Devices
Universal Surgical Mesh has the same intended use and same technological characteristics as the predicate device PROLENE Polypropylene Mesh Nonabsorbable Synthetic.

Clinical/Non-Clinical Studies
The company did not conduct, nor depend on, clinical studies or non-clinical laboratory studies in order to establish substantial equivalence as there is no change to the clinical intended use as compared to the two predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Generic Medical Device, Inc.
% General Medical Device Company
Ms. Monica R. Montanez, RAC, CQA
Consultant
3906 Roseland Street
Houston, Texas 77006

APR 27 2007

Re: K070018
Trade/Device Name: Universal Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 14, 2007
Received: April 17, 2007

Dear Ms. Montanez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

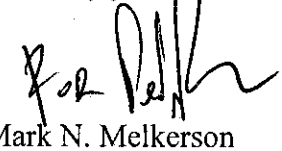
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use
Universal Surgical Mesh

510(k) Number (if known):

Device Name: Universal Surgical Mesh

Indications For Use: The Universal Surgical Mesh is indicated for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070018